

### **III. Remarks**

#### **A. Status of the Application**

Claims 1-8, 11-13, 23, 24, and 27-29 are presently pending in this application. None of the claims are amended by this paper. The claim listing is provided solely for the convenience of the Examiner.

#### **B. Interview Summary**

The Applicant appreciates the courtesies extended by the Examiner in the telephone interview conducted on October 22, 2008. Generally, the anticipation rejection of claim 29 in view of U.S. Patent No. 6,752,832 to Neumann was discussed. In particular, the claim element “an engager device separate from the set of gears and fixedly secured to one of the gears for conjoint rotation therewith” was discussed in view of the disclosure in Neumann.

#### **C. Claim Rejections – 35 USC § 102**

The Final Office Action indicated that claim 29 is rejected under 35 U.S.C. §102(e) as being anticipated by Neumann. Applicant respectfully traverses this rejection.

The PTO provides in MPEP § 2131 that

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (emphasis added)

Neumann discloses a spinal implant comprised of a sleeve 2, inner core part 3, and a nut 4, as shown below in FIG. 2 of Neumann.

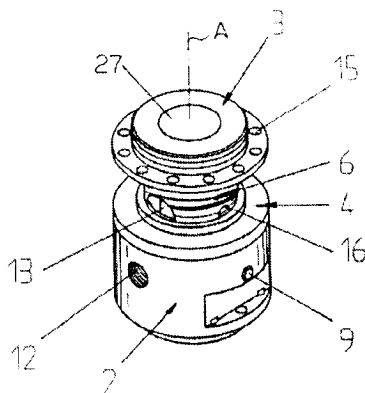


FIG. 2

Referencing FIG. 5 shown below, Neumann teaches that sleeve 2 has inwardly projecting pins 9, notch 10, threaded hole 12, and holder grooves 17.

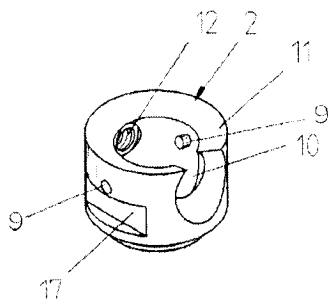


FIG. 5

Neumann further teaches, as shown below in FIG. 3, that inner core part 3 has narrow slots 8, wide slots 13, and external screwthreads 6.

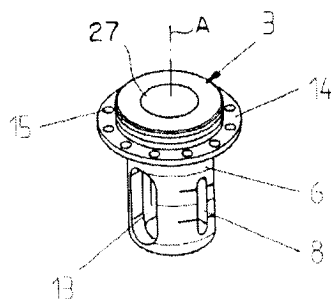
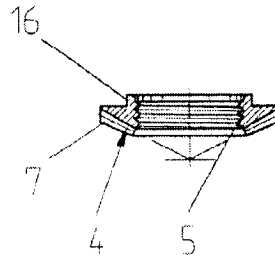


FIG. 3

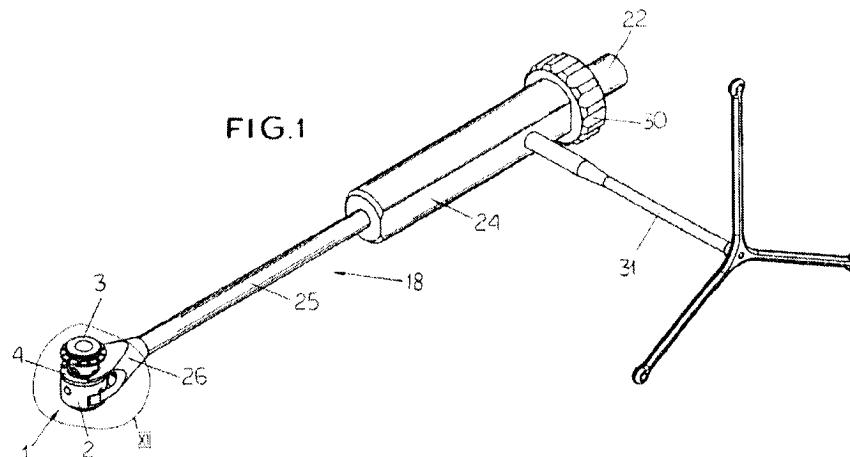
Additionally, as shown below in FIG. 8, Neumann teaches that nut 4 has teeth 7 and internal screwthreads 5.



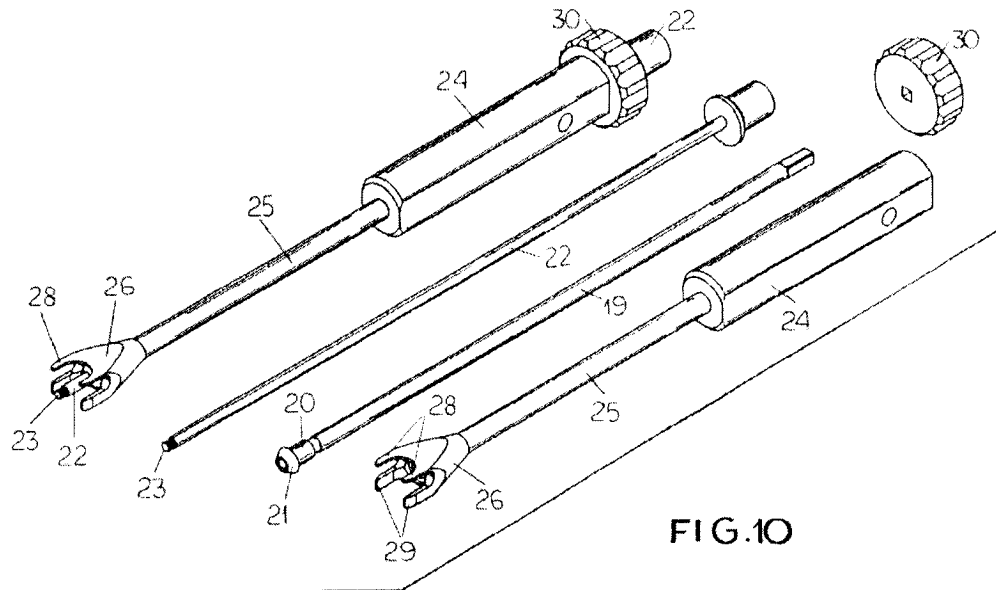
**FIG.8**

Based on the foregoing, Neumann teaches a spinal implant that is assembled as shown above in reproduced FIG. 2. Specifically, Neumann teaches that inner core part 3 is coupled to sleeve 2 by inserting projecting pins 9 of sleeve 2 into narrow slots 8 of inner core part 3. The insertion of pins 9 into narrow slots 8 prevents rotation of sleeve part 2 relative to inner core part 3. Furthermore, Neumann teaches that nut 4 is coupled to inner core part 3 by the engagement of internal screwthreads 5 of nut 4 with the external screwthreads 6 of the inner core part 3. Therefore, Neumann teaches a spinal implant that prevents sleeve 2 from rotating relative to inner core part 3, but allows nut 4 to rotate relative to sleeve 2 and inner core part 3.

Additionally, Neumann teaches using tool 18, as shown below in reproduced FIG. 1 of Neumann, to set and expand the spinal implant 1.



Referencing FIG. 10 shown below, Neumann teaches that tool 18 is composed of rod 22, shaft 19, and outer tube 25.



Specifically, Neumann teaches that rod 22 passes through shaft 19 and shaft 19 passes through outer tube 25 to form tool 18. Additionally, as shown above in FIG. 10, Neumann discloses that the distal end of rod 22 has threads 23. Furthermore, Neumann discloses, as shown above in FIG. 10, that the distal end of shaft 19 has a bevel gear 20 with teeth 21. Finally, Neumann teaches, as shown above in FIG. 10, that the distal end of outer tube 25 has holder 26 with upper fork 28 and lower fork 29.

In practice, Neumann teaches, as shown above in FIG. 1, that spinal implant 1 is inserted within the spine using tool 18. Specifically, Neumann discloses:

To set the implant 1 its parts are fitted together with the nut 4 screwed all the way up on the screwthread [6] of the core part 3 so that the assembly is of minimal axial dimension. It is then fitted to the forks 28 and 29 of the holder 26. This engages the gear 21 on the tubular shaft 19 with the teeth 7 of the nut 4. Then the rod 22 is passed through the slots 13 and its end 23 is screwed into the hole 12. This solidly locks the implant 1 to the inner end of the tool 18.

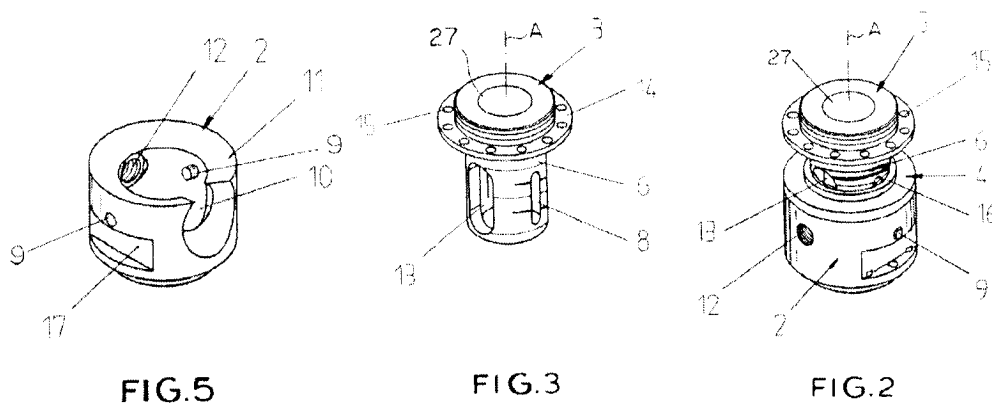
The insert 1 is then moved into position between the two vertebrae it is to brace and, if necessary distract. The wheel 30 is rotated to turn the shaft 19 and gear 21, thereby rotating the nut 4 so that it screws the core part 3 axially away from the sleeve part 2, axially extending the implant.

Once the implant 1 is solidly in place, the [rod 22] is unscrewed from the hole 12 and the tool 18 is pulled radially of the axis A off

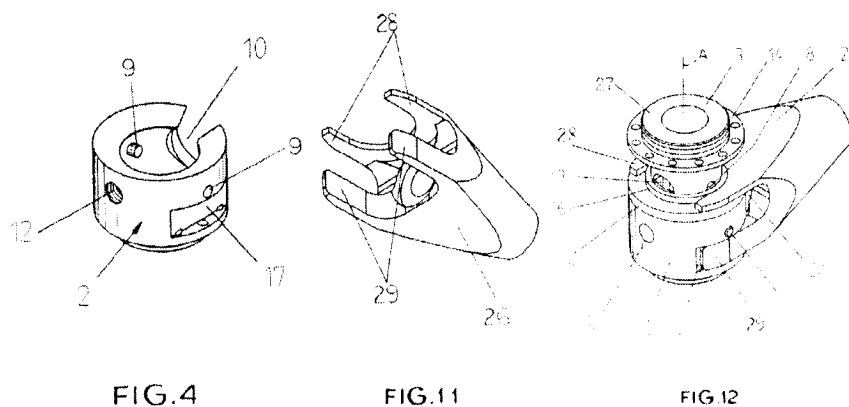
the implant 1, leaving the implant 1 in position.

Neumann, col.4 ll.19-35 (emphasis added).

However, with respect to independent claim 29, Neumann at least fails to disclose an apparatus for installing a vertebral implant assembly including, “an engager device separate from the set of gears and fixedly secured to one of the gears for conjoint rotation therewith.” Based on the above discussion, it is clear that sleeve part 2, which the Final Office Action identifies as the claimed engager, does not conjointly rotate with one of the gears. First, as discussed above and shown below in FIGS. 2, 3, and 5, Neumann teaches that projecting pins 9 of sleeve 2 (FIG. 5) are inserted within narrow slots 8 of inner core part 3 (FIGS. 2 and 3).

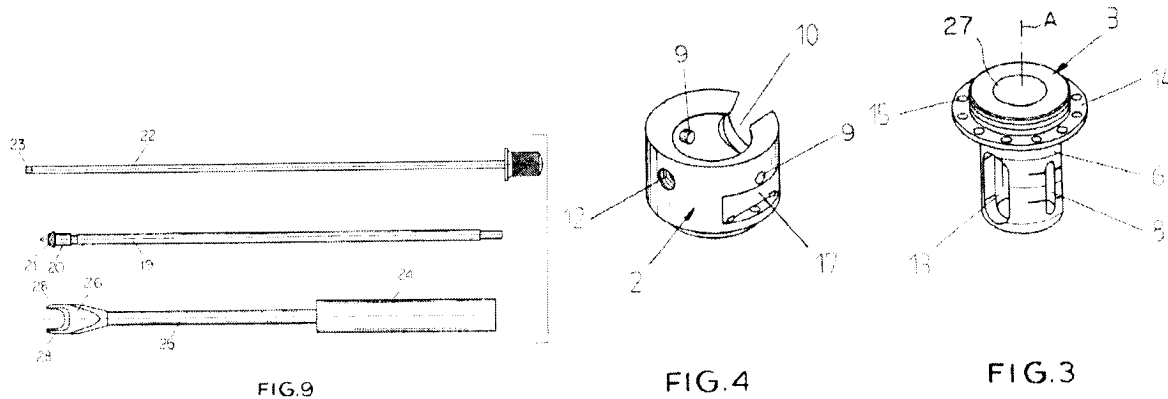


Furthermore, as discussed above and shown below in FIGS. 4, 11, and 12, Neumann additionally teaches that lower fork 29 of holder 26 (FIG. 11) is inserted within grooves 17 of sleeve 2 (FIG. 4) while inserting the spinal implant 1 (FIG. 12).



Therefore, as clearly shown above in FIG. 12, the insertion of lower forks 29 into grooves 17 of sleeve 2 and the insertion of projecting pins 9 of sleeve 2 into narrow slots 8 of inner core part 3 prevent sleeve 2 from rotating while implant 1 is expanded axially using tool 18.

Secondly, as discussed above and shown below in FIGS. 3, 4, and 9, Neumann further teaches that rod 22 (FIG. 9) is positioned through notch 10 of sleeve 2 (FIG. 4), then through wide slots 13 of inner core part 3 (FIG. 3), and then screwed into hole 12 of sleeve 2 (FIG. 4).



Neumann explicitly states this positioning of rod 22 occurs while shaft 19 (FIG. 9) is rotating gears 21 to axially expand spinal implant 1. *See* Neumann, col.4 ll.19-35. Consequently, sleeve part 2 does not conjointly rotate with gear 21 because rod 22 is inserted through sleeve part 2 and inner core member 3 and subsequently screwed into sleeve part 2 while implant 1 is expanded axially.

No other element or component of Neumann meets all the features of the claimed engager. Thus, Neumann fails to disclose “an engager device separate from the set of gears and fixedly secured to one of the gears for conjoint rotation therewith,” as required by independent claim 29. For at least these reasons, claim 29 rejected on the basis of Neumann is in condition for allowance.

### C. Claim Rejections – 35 USC § 103

#### 1. *The Neumann and Mauldin Patents*

The Final Office Action indicated claims 1-8 and 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Neumann in view of U.S. Patent No. 5,732,992 to Mauldin. Applicant traverses the rejection of claims 1-8 and 11-13 on the grounds that the combination of Neumann and Mauldin is defective in establishing a *prima facie* case of obviousness with respect to these claims.

35 U.S.C. §103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .” (emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

With respect to independent claim 1, however, the combination of Neumann and Mauldin fails to teach or suggest an apparatus for installing a vertebral implant assembly including, “an engager device connected to the set of gears and adapted to rotate the tubular body when the axle is rotated.” As previously discussed above, the sleeve part 2, which the Final Office Action identified as the claimed engager, does not rotate for two mutually exclusive reasons. First, the insertion of lower forks 29 of holder 26 into grooves 17 of sleeve 2 in combination with the insertion of projecting pins 9 of sleeve 2 into narrow slots 8 of inner core part 3 prevents sleeve 2 from rotating while implant 1 is expanded axially. Secondly, sleeve 2 does not rotate because rod 22 is positioned through notch 10, wide slots 13, and screwed into hole 12 while implant 1 is expanded axially. Instead, Neumann discloses that wheel 30 is rotated to turn the shaft 19 and gear 21, which the Final Office Action labels as the “axle” and “gear” respectively, to rotate the nut 4, so that it screws the inner core part 3 axially away from the sleeve part 2. Therefore, Neumann fails to teach or suggest an engager device as recited in claim 1. Mauldin does not remedy this deficiency, because Mauldin entirely fails to teach or suggest any engager device meeting the recited features of claim 1. Mauldin is relied on only for a teaching of movable arc portions with substantially smooth surfaces, and that teaching is not relevant here.

Thus, the combination of Neumann and Mauldin fails to teach or suggest “an engager device connected to the set of gears and adapted to rotate the tubular body when the axle is rotated.” For at least these reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 1.

Claims 2-8 and 11-13 depend from and further limit independent claim 1. Therefore, a *prima facie* case of obviousness has not been established with respect these dependent claims. Thus, the Applicant respectfully requests that the §103 rejection of claim 1-8 and 11-13 over

Neumann in view of Mauldin be withdrawn.

*2. The Neumann and Zacouto Patents*

The Final Office Action indicated claims 23, 24, 27, and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Neumann in view of U.S. Patent No. 6,692,495 to Zacouto. Applicant traverses the rejection of claims 23, 24, 27, and 28 on the grounds that the combination of Neumann and Zacouto is defective in establishing a *prima facie* case of obviousness with respect to these claims.

With respect to independent claim 28, the combination of Neumann and Zacouto fails to teach or suggest an instrument for installing a vertebral implant including the feature of “wherein rotation of the axle is operative, via rotation of the circumferentially spaced teeth received in the tubular body side wall openings, to rotate the tubular body relative to the pair of endplates.” The Final Office Action does not identify circumferentially spaced teeth within Neumann or Zacouto. Furthermore, with respect to Neumann, the projecting pins 9 of the sleeve part 2 cannot be considered the circumferentially spaced teeth because the sleeve part 2 does not rotate when wheel 30 is rotated to turn the shaft 19 and gear 21. Instead, when wheel 30 is rotated to turn the shaft 19 and gear 21, nut 4 is rotated to screw inner core part 3 axially away from sleeve part 2. Zacouto does not cure this deficiency because Zacouto also fails to teach or suggest the recited feature. Zacouto is relied on only for a teaching of two gears that are perpendicular to one another, and that teaching is not relevant here.

Thus, the combination of Neumann and Zacouto fails to teach or suggest “wherein rotation of the axle is operative, via rotation of the circumferentially spaced teeth received in the tubular body side wall openings, to rotate the tubular body relative to the pair of endplates.” For at least these reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 28.

Claims 23, 24, and 27 depend from and further limit independent claim 28. Therefore, a *prima facie* case of obviousness has not been established with respect these dependent claims. Thus, the Applicant respectfully requests that the §103 rejection of claim 23, 24, 27, and 28 over Neumann in view of Zacouto be withdrawn.

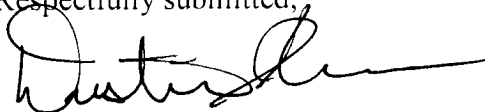


#### IV. Conclusion

In view of the foregoing remarks, all of the claims currently pending in this application are now seen to be in a condition for allowance. A Notice of Allowance of Claims 1-8, 11-13, 23, 24, and 27-29 is therefore earnestly solicited.

The Examiner is hereby requested to telephone the undersigned attorney of record at 972/739-6969 if such would further expedite the prosecution of the instant application.

Respectfully submitted,



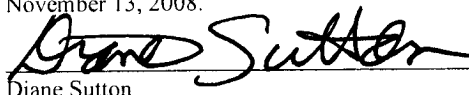
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Diane Sutton